In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1143V

UNPUBLISHED

CATHERINE JONES, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: July 20, 2022 Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Flu Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Terrence Kevin Mangan, Jr., U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On August 6, 2019, Catherine Jones filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleged that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") administered on October 31, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After a review of the record and other filings, and for the reasons discussed below, I find that Petitioner's flu vaccine was administered to her right arm, and that the onset of her right shoulder pain likely began within the 48-hour timeframe required to establish a Table SIRVA claim.

I. Relevant Procedural History

Ms. Jones filed her petition for compensation along with medical record exhibits from August to December 2019. (ECF No. 1, 11-12). Nearly one year later, on November 25, 2020, Respondent filed a status report stating that he did not believe engaging in settlement discussions was appropriate and proposed filing his Rule 4(c) Report. (ECF No. 20). That report was filed on January 25, 2021 (ECF No. 21).

Respondent argued in the Rule 4(c) Report that Petitioner's Table SIRVA claim failed because her vaccination record stated that she received the flu vaccine in her left shoulder, instead of her right shoulder as the petition alleges. *Id*. at 5. In addition, Respondent argued that Petitioner has not established that the onset of her shoulder pain began within 48 hours after receiving her flu vaccination on October 31, 2016. Respondent's Report at 5-6. Respondent noted that Petitioner did not report shoulder pain to any medical provider for more than four months after vaccination. *Id*. at 6. In the interim, Petitioner saw her primary care provider on December 8, 2016 (a little over a month after vaccination), but did not report any shoulder pain. *Id*.; Ex. 2 at 46.

The parties subsequently filed briefing requesting a ruling on situs and onset. My ruling is set forth below.

II. Issue

The following issues are contested: (1) whether Petitioner received the vaccination alleged as causal in her right arm; and (2) whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(c)(10)(ii)-(iii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record.

§ 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). However, the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum*. *Servs*., 997 F.3d 1378, 1383 (Fed. Cir. 2021). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the

injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact

A. Site of Vaccination

Based on a review of the entire record, including all medical records and affidavits, the arguments in Respondent's Rule 4(c) Report, the arguments in Petitioner's Motion for Fact Ruling ("Motion"), and the arguments in the response thereto ("Response"), I find that Petitioner's October 31, 2016 flu vaccine was more likely than not administered in her right arm, as she contends.

Only the initial vaccination record indicates that Ms. Jones received the flu vaccine to her left shoulder. Ex. 15 at 10. All other medical records, however, document Ms. Jones's report that she received the flu vaccine to her right shoulder. Not a single record (other than the vaccination record) contradicts her assertion. *See e.g*., Ex. 2 at 44 (March 7, 2017, "The patient…presents with a shoulder problem. The injury involved the right shoulder…. Mrs. Jones comes in today with several months of shoulder pain. This started after her flu shot"); Ex. 3 at 5 (March 14, 2017, "Catherine Jones is a 87 year old female who presents to therapy today for evaluation of R[ight] Adhesive Capsulitis… Shoulder has been problematic since October 2016. [P]t attributes this to getting her flu shot…"); Ex. 4 at 7 (May 4, 2017, "Catherine R Jones presents to the office for evaluation of her right shoulder. She presents accompanied by her daughter and notes that her shoulder pain presented following a flu shot on 10/31/16"). Ms. Jones confirmed in her affidavit that she received the flu vaccine on October 31, 2016, to her right shoulder. Ex. 18 at 1.

The overall medical records, coupled with Petitioner's affidavit, establish that Petitioner consistently and repeatedly reported to treaters right shoulder pain that was caused by a flu vaccine received *in that shoulder*. These records provide sufficient evidence that the vaccine was likely administered in Petitioner's right shoulder to overcome the contrary administration record (which lacks corroboration on its own). The subsequent treatment records gain strength as well given their temporal proximity to the

date of vaccination. And there is no reason to give the single record of vaccine administration more weight simply because it came first, in the absence of other evidence that corroborates it.

B. Onset

I also find that the record evidence preponderates (albeit barely) in Petitioner's favor on the disputed onset issue. I find the following facts most relevant:

- Petitioner's pre-vaccination records reveal a history of hypertension, degenerative joint disease (of the back and neck areas), abdominal aortic aneurysm, dyslipidemia, and osteopenia.

- Ms. Jones suffered a right shoulder dislocation in 2012 (Ex. 13 at 20). Petitioner states that the injury resolved in 2012 (Ex. 13 at 21) and she received no further treatment. Ex. 14 at 2. The medical records corroborate her statement, making no mention of injuries, inflammation, or dysfunction of the right shoulder or arm in the three years prior to vaccination. *See generally* Ex. 2.

- On October 31, 2016, Ms. Jones (87 years-old) received a flu vaccine at CVS Pharmacy located in Farmville, Virginia. Ex. 15 at 10. The vaccination record states that the vaccine was administered to Petitioner's left deltoid. *Id*.

- On December 8, 2016, 38 days after vaccination, Petitioner saw her primary care physician ("PCP"), Dr. Danielle Lewis, for a follow-up appointment regarding hypertension and cholesterol. Ex. 2 at 46. During this visit, Ms. Jones complained of right knee pain "occurring in a persistent pattern for weeks." *Id. Id.* There is no documented complaint of shoulder pain during this visit. *Id.*

- On March 7, 2017 (4 months, 7 days after vaccination), Petitioner presented to Dr. Lewis complaining of shoulder pain. Dr. Lewis noted shoulder pain, tenderness, frozen shoulder, and decreased range of motion. The note indicated "onset was sudden month(s) ago… Ms. Jones comes in today with several months of shoulder pain. This started after her flu shot. Her shoulder has been stiff and painful." Ex. 2 at 44. Petitioner was diagnosed with adhesive capsulitis. *Id*. at 45.

- One week later, on March 14, 2017, Petitioner presented to physical therapist ("PT"), Zachary Wood, at Centra Rehabilitation with complaints of shoulder pain. PT Wood noted "Shoulder has been problematic since October 2016. [P]t attributes this to getting her flu shot…" Ex. 3 at 5. On examination, Petitioner

demonstrated “limited and painful ROM [range of motion] during eval[uation]. MMT weak and painful in her R arm.” *Id*. at 7. PT Wood also noted that Petitioner’s prior right shoulder dislocation “may impact overall prognosis.” *Id*.

- On May 4, 2017, Ms. Jones was evaluated by Dr. John Barnard at OrthoVirginia located in Prospect, Virginia. Dr. Barnard noted “Catherine R Jones presents to the office for evaluation of her right shoulder. She presents accompanied by her daughter and notes that her shoulder pain presented following a flu shot on 10/31/16. She noted immediate pain that has not subsided. She initially presented to her PCP who diagnosed her with adhesive capsulitis. She was treated with formal PT without benefit. She notes that she discontinued PT about 3 weeks ago. She localizes her pain at the mid to upper anterior upper arm radiating along her biceps muscle belly. She notes that her pain is worse at night and often keeps her from sleep. She notes a previous right shoulder dislocation that was treated by Dr. Wombwell. She denies any numbness or tingling.” Ex. 4 at 7. Dr. Barnard assessed Petitioner with adhesive capsulitis of the right shoulder, complete tear of the right rotator cuff, and right shoulder pain. *Id*. at 8. Dr. Barnard notes “I suspect that she has neuritis secondary to her flu shot with a secondary mild frozen shoulder. She has a cuff tear that is unrelated to her flu shot but it most likely related to her previous dislocation. We will treat her for both.” *Id*.

- On June 15, 2017, during an appointment with Dr. Lewis, Petitioner still complained of right shoulder pain with movement, although there was no decrease in range of motion noted. Ex. 2 at 40.

- On April 23, 2018, Dr. Lewis noted that Petitioner was still complaining of shoulder pain. Dr. Lewis noted “CHRONIC PAIN OF UPPER EXTREMITY: This has been for 1.5 years since October 2016. This was caused by improper administration of the influenza vaccine into her nerve. The technician reached across a counter to give the vaccine and hit a nerve. She has had limited range of motion and strength in that arm since that time. She has been unable to sleep on her right side due to pain. she has undergone an extensive evaluation by orthopedics for this. Her symptoms have never completely resolved.” Ex. 2 at 33.

- On October 15, 2018, Ms. Jones complains to Dr. Lewis that she “still ha[d] right shoulder pain with certain movements. Her range of motion is full, but she experiences significant pain with abduction. She began having pain after an injury from flu vaccine. The flu vaccine was injected into the nerve about two years ago.” Ex. 2 at 15.

The disputed onset issue presents a very close call. However, the filed evidence (which includes both medical records and Petitioner's witness statements) preponderates in favor of the conclusion that onset of her injury likely occurred close-in-time to vaccination.

Admittedly, Respondent has raised a valid concern regarding the length of time after vaccination that the injury is first documented in the medical records, as well as the existence of an intervening instance in which shoulder pain was not mentioned. The most problematic record is that from her December 8, 2016 appointment with Dr. Lewis, which occurred 38 days after vaccination. Ex. 2 at 46. In this record, Ms. Jones is being seen in follow up for her hypertension and cholesterol, and she complained only of right knee pain. In her affidavit, however, Ms. Jones states that she did, in fact, complain to Dr. Lewis of right shoulder pain since her flu vaccine, but Dr. Lewis "did not seem overly concerned" about it and stated that "it would go away." Ex. 18 at 2. She also explains that she delayed mentioning shoulder pain until this point because this was when her next appointment with Dr. Hughes was scheduled; she was 87 years old at the time and relied on her daughter to drive her to and from her medical appointments. *Id.* at 1.

Besides the above, other evidence is also consistent with Petitioner's onset contentions. For example, Ms. Jones maintains that one day after vaccination, she returned to CVS Pharmacy and complained to the pharmacist of her right shoulder pain, but was told that "[t]his happens sometimes and it would get better." Ex. 18 at 1. Petitioner's daughter, Debra Tharp – a licensed practical nurse – has also recalled that her mother complained of "extreme pain and redness" to her right shoulder on November 1, 2016 - the day she received her flu shot. Ex. 17 at 1.

There is no dispute that Ms. Jones did not suffer from any right shoulder symptoms in the three years prior to receiving the flu vaccine in October 2016. There is also no evidence of any intervening injury or trauma in the medical records between October 2016 and March 2017 that would explain the sudden onset of her right shoulder pain and resulting adhesive capsulitis. And the record corroborates the fact of subsequent injury – even though, admittedly, there are no close-in-time treatment records. I also credit Ms. Jones's statement in her affidavit that she reported right shoulder pain to Dr. Lewis in December 2016, but her complaints were not taken seriously.

Another factor that weighs in favor of a finding of 48-hour onset right shoulder pain is the absence of any statement or record that places the onset of Ms. Jones's right shoulder pain *outside* the 48-hour window. Rather, Respondent can only point to instances where onset, or the injury itself, is omitted. By contrast, there are at least *five* different records where Ms. Jones reports that her pain began on, or immediately after, the day of vaccination. *See,* e.g., Ex. 2 at 44 ("onset was sudden month(s) ago… Ms. Jones comes in today with several months of shoulder pain. This started after her flu shot.

Her shoulder has been stiff and painful"); Ex. 3 at 4 ("Shoulder has been problematic since October 2016. [P]t attributes this to getting her flu shot…"); Ex. 4 at 7 ("Catherine R Jones presents to the office for evaluation of her right shoulder. She presents accompanied by her daughter and notes that her shoulder pain presented following a flu shot on 10/31/16. She noted immediate pain that has not subsided…"); Ex. 2 at 33 ("CHRONIC PAIN OF UPPER EXTREMITY: This has been for 1.5 years since October 2016. This was caused by improper administration of the influenza vaccine into her nerve…"); Ex. 2 at 15 ("She began having pain after an injury from flu vaccine. The flu vaccine was injected into the nerve about two years ago.")

Unquestionably, the four-month records gap from vaccination to the first efforts to treat Ms. Jones's alleged shoulder pain is problematic for Petitioner's case. As Respondent argues, it is reasonable to expect that the average Program claimant might seek medical treatment sooner if in fact the person was experiencing sudden post-vaccination pain. However, as noted above, claimants may often misperceive the extent of their shoulder injury, or downplay its significance, leading them to delay treatment. *See, e.g.*, *Williams v. Sec'y of Health & Human Servs.*, No. 17-830V, 2019 WL 1040410, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because petitioner underestimated the severity of her shoulder injury); *Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. March 30, 2018), *review denied*, 142 Fed. Cl. 329 (2019) (finding a 48-hour onset of shoulder pain despite a nearly six-month delay in seeking treatment); *Marino v. Sec'y of Health & Human Servs.,* No. 16-622V, 2018 WL 2224736, at *2 (Fed. Cl. Spec. Mstr. Mar. 26, 2018) (noting a delay in seeking treatment for several months due to petitioner's work schedule and difficulty making appointments); *Knauss v. Sec'y of Health & Human Servs.*, No. 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018) (noting a three-month delay in seeking treatment).

Here, as in other cases, Respondent argues that a special master cannot rely on the statements of the petitioner alone regarding a key element like onset. *See e.g., Juno v. Sec'y of Health & Human Servs*., No. 18-643, 2021 WL 4782691, at * 5 (Fed. Cl. Spec. Mstr. Sept. 13, 2021). But the Federal Circuit has expressly recognized that witness testimony on issues pertaining to fact matters *can* be proven by reliance on testimonial evidence (even if that testimonial evidence must be weighed against the records themselves, which continue to have evidentiary significance). *Kirby*, 997 F.3d at 1383. Respondent has not identified any inconsistencies or discrepancies in the medical records. And in this case, the relevant witness statements are not the only evidence in favor of an onset finding consistent with a Table SIRVA claim. I am therefore not "solely" relying on witness statements.

At bottom, the evidence preponderates, although just barely, in favor of a determination that onset began in 48 hours of vaccination. Of course, the fact of Petitioner's delay in obtaining will bear on any damages to be awarded in this case, since it either establishes a SIRVA mild enough to be tolerated for a long time, or Petitioner's own contributions to severity. But these considerations are separate from whether onset occurred when Petitioner alleges.

C. Prior Right Shoulder Dislocation – Alternative Cause

The parties specifically requested that I rule on the issue of situs and onset in their briefing. However, it appears that Petitioner also request that I rule on entitlement (Petitioner's Reply, ECF No. 29), although his initial motion only sought a factual ruling. While I will not specifically rule on entitlement in this ruling, I will address the alternative cause issue that Respondent has raised - that Ms. Jones's prior shoulder dislocation is the cause of her recent shoulder injury. Response at 5.

Based on the information contained in the medical records, I find that it was more likely than not that Petitioner's prior shoulder dislocation did *not* cause her recent shoulder symptoms and injury after vaccination. In the three years prior to receiving the October 31, 2016 flu vaccination, there is no mention of any right shoulder pain, injuries, or symptoms. In her affidavit, Ms. Jones stated that her shoulder dislocation injury was treated and resolved in 2012, and the medical records support her statement. Ex. 13 at 21. While her prior dislocation may have affected her "overall prognosis" as her physical therapist indicated (Ex. 3 at 5), the evidence preponderantly demonstrates that it did not cause her most recent injury as Ms. Jones was asymptomatic for at least three years prior to vaccination. I thus find that there is no history of pain, inflammation or dysfunction of Petitioner's affected shoulder that would explain her symptoms after vaccination.

D. Scheduling Order

Given my findings of fact, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Accordingly, the following is ORDERED:

(1) By <u>Monday, August 26, 2022,</u> Petitioner shall file all updated medical records.

(2) Respondent shall file, by no later than <u>Monday, September 19, 2022,</u> an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding.

IT IS SO ORDERED.

<u>s/Brian H. Corcoran</u>
Brian H. Corcoran
Chief Special Master